

December 28, 2001

Administrator  
US Environmental Protection Agency  
P.O. Box 1473  
Merrifield, VA 22116  
Attention: Chemical Right-to-Know Program

Registration Number: [REDACTED]

Dear Administrator Whitman:

FMC Corporation actively supports the EPA HPV Challenge Program, AR-201 and is pleased to submit the proposed test plans and robust summaries for the two single chemicals:

- Phenol, 2-[(2-methyl-2-propenyl) oxy]; Methallyloxyphenol – CAS No. 4790-71-0
- Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester -- CAS No. 61898-95-1

In addition to the above referenced two single chemicals, FMC's HPV Challenge commitment to EPA for 2001 included the single chemical Orthoacetic acid, trimethyl ester (TMOA) – CAS No. 1445-45-0. Please note that FMC respectfully requested the withdrawal of Orthoacetic acid, trimethyl ester (TMOA) from the program in a correspondence dated September 13, 2001 to EPA (Ms. Linda M. Clark to Chemical RTK Program). It came to FMC's attention that our sole foreign supplier of TMOA, Degussa-Huls AG, committed to test this chemical in the ICCA chemical testing initiative regarding High Production Volume chemicals as stated by Degussa-Huls AG in their letter to EPA dated January 25, 2000. EPA assigned this letter the code AR201-12311. FMC, therefore, withdrew support of TMOA given the fact it is being tested in the ICCA HPV program.

FMC proposes Closed System Intermediate Status for the two single chemicals and information supporting exemption claims for Reduced SIDS Testing has been prepared. Please note for the single chemical, Phenol, 2-[(2-methyl-2-propenyl) oxy]; Methallyloxyphenol, the test plan for aquatic toxicity indicates testing for estuarine species and not freshwater species as the potential for exposure at the manufacturing site where the chemical undergoes reaction is to estuarine species. This rationale was discussed with Mr. Richard Hefter, Chief of the HPV Chemicals Branch with verbal approval given FMC on October 3, 2001. Additionally, FMC plans to submit documentation supporting Closed System Intermediate Status for Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester as soon as received from the FMC customer.

This submission includes one electronic copy of documents in *Microsoft Word 97* and *IUCLID* formats. FMC understands there will be a 120-day review period for the test plan and that all comments received by EPA will be forwarded to FMC for consideration. Please contact me if you have comments or questions regarding this submission.

Sincerely,

LuAnn Maloney  
For FMC Corporation  
Tel. 215.299.6680 Fax 215.299.6468

## TEST PLAN

**Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester**  
**CAS No. 61898-95-1**

STUDY	INFORMATION (Yes or No)	OECD STUDY (Y/N)	GLP (Y/N)	OTHER STUDY (Y/N)	ESTIMATION METHOD (Y/N)	ACCEPTABLE (Y/N)	SIDS TESTING REQUIRED (Y/N)
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### Physical and Chemical Data

Melting Point	No						No
Boiling Point	Yes	No	No	Yes	No	Yes	No
Vapor Pressure	Yes	No	No	Yes	No	Yes	No
Partition Coefficient	No						Yes
Water Solubility	Yes	No	No	Yes	No	Yes	No

### Environmental Fate

	Yes	No	No	No	Yes	Yes	No
Photodegradation	Yes	No	No	No	Yes	Yes	No
Biodegradation	No						Yes
Fugacity	Yes	No	No	No	Yes	Yes	No

### Ecotox

Acute Toxicity to Fish – Rainbow trout	Yes	No	Yes	No	No	Yes	No
Toxicity to Algae	Yes	Yes	Yes	No	No	Yes	No
Acute Toxicity to Daphnia	Yes	No	Yes	No	No	Yes	No

### Toxicity

Acute Oral	Yes	No	Yes	No	No	Yes	No
Acute Inhalation	Yes	No	Yes	No	No	Yes	No

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# TEST PLAN (continued)

Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester  
CAS No. 61898-95-1

STUDY	INFORMATION (Yes or No)	OECD STUDY (Y/N)	GLP (Y/N)	OTHER STUDY (Y/N)	ESTIMATION METHOD (Y/N)	ACCEPTABLE (Y/N)	SIDS TESTING REQUIRED (Y/N)
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## Toxicity

Genotoxicity <i>In Vitro</i> (Bacterial Test)	Yes	No	Yes	No	No	Yes	No
Genotoxicity <i>In Vitro</i> (Mammalian Cells)	No						Yes
Repeated Dose	No						No*
Reproductive Toxicity	No						No*
Developmental Toxicity	No						Yes*

- Reduced testing requirements for Closed-System Intermediates. Actual initiation of Developmental Toxicity Testing is deferred until 2003 as instructed by EPA guidance.

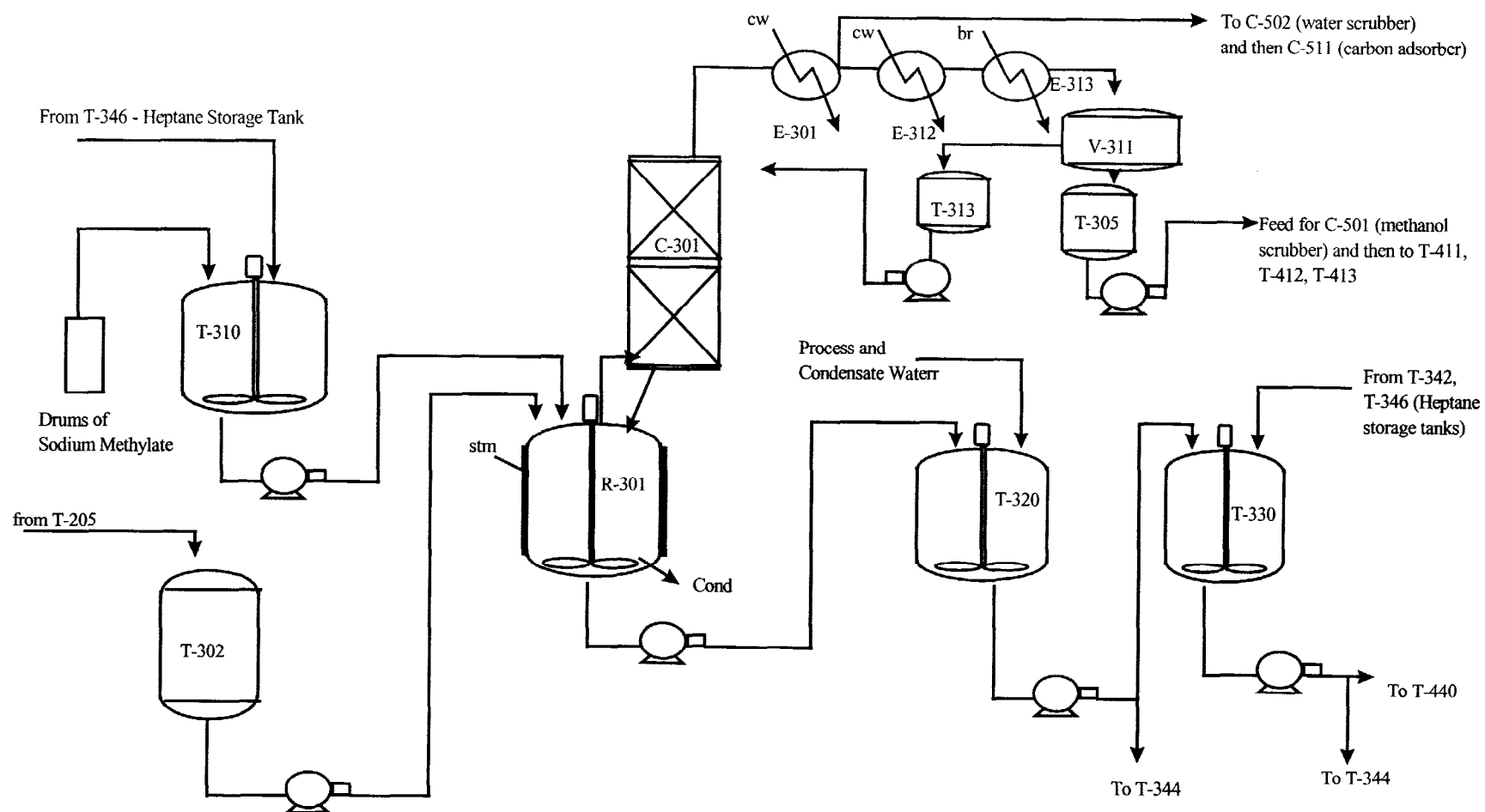
Methyl DVEster is produced at the B-34 facility in the FMC Baltimore Plant.

### Process Description

Step II product (FMC 30099) and sodium methylate are reacted to produce DVester (FMC 39338) in a batch reaction. Figure 1 shows the Step III reaction system.

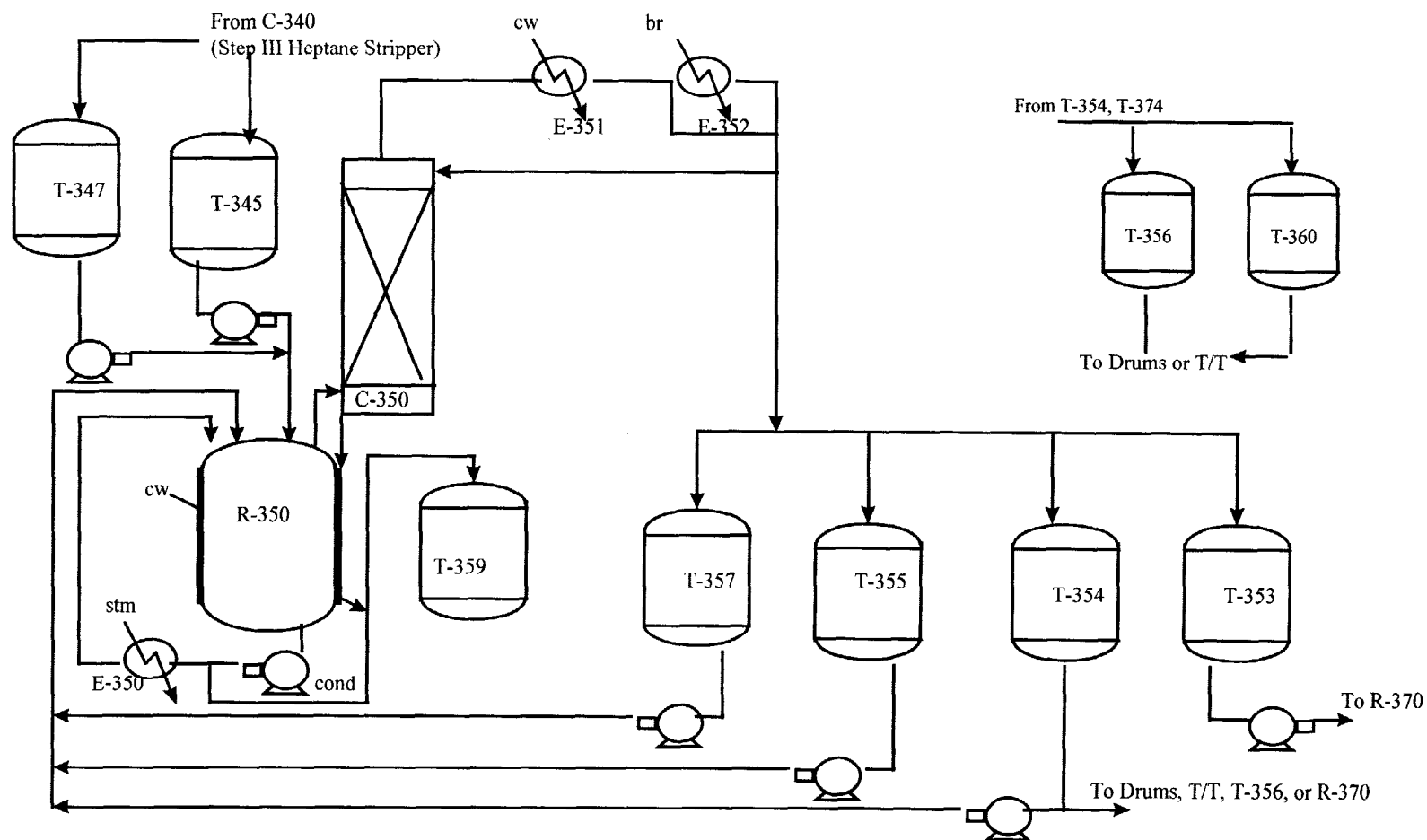
Step III product is washed with process water and steam jet condensate water to remove sodium chloride salt from the organics. The organic layer is pumped to the heptane stripper. All aqueous streams from the DVester process are collected in a storage tank which is filtered and sent to on-site wastewater treatment before discharge to the Publicly Owned Treatment Works (POTW).

The heptane stripper continuously removes heptane from the crude washed DVester. The crude DVester bottoms is pumped to an intermediate storage tank. Finished goods quality DVester is distilled in the Step III distillation system. The DVester product cut is then taken to intermediate storage. DVester is loaded onto tank trucks or drummed.



T-205 Step II Product Storage Tank	T-310 Sodium Methylate Slurry Charge Tank	T-301 Step III Reactor Column	E-301 Step III Reactor Condenser	E-313 Step III Reactor After Condenser	V-311 Step III Reactor Decanter	T-320 Step III Wash Tank	T-330 Step III Extraction Tank	T-440 Waste Water Storage Tank
	T-302 Step III Product Feed Tank	R-301 Step III Reactor	E-312 Step III Chiller	T-313 Reflux Surge Tank	T-305 Waste Methanol Surge Tank	T-344 Heptane Stripper Feed Tank	T-411, 412, 413 Waste Methanol Storage Tanks	

## DVEster Distillation



T-347  
Crude DVEster  
Tank

T-345  
Crude DVEster  
Tank

C-350  
DVEster Distillation  
Column

E-351  
DVEster Distillation  
Condenser

T-357  
Low Assay  
Receiver

T-354  
DVEster Product  
Receiver

T-356  
DVEster Blend  
Tank

T-359  
Bottom Tank

E-350  
DVEster Distillation  
Reboiler

R-350  
DVEster Distillation  
Pot

E-352  
DVEster Distillation  
Aftercondenser

T-355  
Low Cis  
Receiver

R-370  
DVEster  
Utility Still

T-353  
CA's Cut  
Receiver

T-360  
DVEster Blend  
Tank

## Monitoring Data

### **Wastewater monitoring**

All aqueous streams from the DVEster process are collected in a storage tank which is filtered and sent to on-site carbon treatment before discharge to the POTW. Wastewater samples are taken before every pump down to the south plant carbon beds. In 2001, the average concentration of DVEster in this wastewater stream has been 678 ppm.

**IH Data** – IH monitoring was conducted in 1987, 1988, 1989 and 1991 to establish guidelines and confirm trends.

The 1987 data was a B-34 wide collection of area and personal breathing zone samples. DVEster was non detectable (limit of detection 0.5 ppm) with a guideline (FMC) of 6 ppm. In 1998, no detectable amounts of DVEster were found during the drumming of DVEster. The limit of detection was 0.5 ppm, and area and personal breathing zone samples were taken. In 1989, additional monitoring during DVEster drumming was conducted with no detectable amounts of DVEster found. In 1990, personal breathing zone sampling was conducted along with a general area sample. No detectable amounts of DVEster were found. In 1991, personal breathing zone and a general area sample was taken during DVEster drumming. DVEster levels measured averaged non detectable to 2.1 ppm with a limit of detection at 0.5 ppm.

#### Presence in Distributed Product and in End Use Products

DVEster is listed as an impurity with a maximum allowable level as stated in the following FMC technical products Confidential Statement of Formula (CSF):

Technical	DVEster Maximum Allowable Level (CSF) , %	2001 Average DVEster Impurity in Tech, %
Cypermethrin	1.5	0.58
Permethrin	2.0	0.60
Zeta-cypermethrin	4.0	0.92

#### Transport Data

DVEster is loaded onto tank trucks or drummed.

During 2001, DVEster has been transported by drum and tank truck on the FMC Baltimore facility. Within the FMC facility, DVEster is used in the production of insectide intermediates and technical products.

Also during 2001, DVEster has been transported within the United States to Zeneca in Cold Creek, Alabama. Zeneca arranges for the shipping company to handle the transport of the DVEster from the Baltimore site.

DVEster is also shipped internationally to a number of customers.

#### Data Search

Results from a literature search to support this closed system intermediate claim will be submitted as an addendum.



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**PHYSICAL AND CHEMICAL DATA**

**1. MELTING POINT**

The material is a liquid at room temperature. See Boiling Point.

**2. BOILING POINT**

Test Substance: Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2-2-dimethyl-, methyl ester

Method: Distillation

GLP: No

Year: 1981

Results: 78 °C at 0.6 mm Hg

Data Quality: 4b

References: FMC Chemical Data Sheet No. 174, Revision 1, 1981

**3. VAPOR PRESSURE**

Test Substance: Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2-2-dimethyl-, methyl ester

Method: Gas saturation technique, mathematical extrapolation from higher temperature data

GLP: No

Year: 1981

Results: 0.03 mm Hg at 25 °C

Data Quality: 4b

References: FMC Chemical Data Sheet No. 174, Revision 1, 1981

**4. PARTITION COEFFICIENT**

No data available

**5. WATER SOLUBILITY**

Test Substance: Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2-2-dimethyl-, methyl ester

Method: Shake flask/gas chromatography

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Temperature: 25 °C  
GLP: No  
Year: 1998  
Results: 53 µg/mL  
Data Quality: 4b  
References: FMC Memorandum, M. Alvarez to W. W. Smith, 6/16/98

## **ENVIRONMENTAL FATE AND PATHWAY**

### **6. PHOTODEGRADATION**

Test Substance: Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-  
2-2-dimethyl-, methyl ester

Method: Estimated by the AOP program (v. 1.90) which estimates rate constants and half-lives of atmospheric reactions of organic compounds with hydroxyl radicals and ozone in the atmosphere.

GLP: No

Year: 2000

Results: For reaction with hydroxyl radicals, the predicted half-life is 2.4 days with a rate constant of  $4.46 \times 10^{-12}$  cm<sup>3</sup>/molecule-sec.

Remarks: The photodegradation calculation by an acceptable method is assigned a reliability code of 2f.

References: AOPWIN version 1.90, Syracuse Research Corporation, Syracuse, NY

### **7. STABILITY IN WATER (HYDROLYSIS)**

Test Substance: Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-  
2-2-dimethyl-, methyl ester

Method: Estimated by HYDROWIN program (v. 1.67)

GLP: No

Year: 2000

Results: This compound was predicted to undergo base hydrolysis.  
Rate constant (pH>8, 25°C): 1.27E-2 L/mol-sec  
Half-life at pH 8: 1.7 years  
Half-life at pH 7: 17 years

Remarks: The hydrolysis calculation by an acceptable method is assigned a reliability code of 2f.

References: HYDROWIN version 1.67, Syracuse Research Corporation, Syracuse, NY

#### 8. TRANSPORT/DISTRIBUTION (FUGACITY MODEL)

Test Substance: Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester

Method: Estimated by EPIWIN program (v. 3.05) Level III Fugacity Model

GLP: No

Year: 2001

Results: Distribution using Level III Fugacity Model

Air	3.53%
Water	21.5%
Soil	73.6%
Sediment	1.34%

Remarks: Code 2f

References: EPIWIN version 3.05, Syracuse Research Corporation, Syracuse, NY

#### 9. BIODEGRADATION

No data available

### ECOTOXICOLOGY

#### 10. ACUTE TOXICITY TO FISH

Test Substance: Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester (99.3%)

Method: U.S. EPA FIFRA 72-1 (c)

The acute toxicity under static renewal conditions of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester to the rainbow trout (*Oncorhynchus mykiss*), was conducted for FMC Corporation for 96-hours from May 24 to 28, 1999 at T.R. Wilbury Laboratories, Inc., in Marblehead, Massachusetts.

The test was performed at 12 +/- 1°C with five concentrations of test substance and a dilution water control. The dilution water was deionized water collected at Marblehead, MA and adjusted to a hardness of 40 to 48 mg/L as CaCO<sub>3</sub>. Dissolved oxygen, pH, conductivity, temperature were measured and

recorded daily in each test chamber that contained live animals. Measurements were made before and after media renewal at 24, 48, and 72 hours.

Juvenile rainbow trout were obtained from a single source and were identified using an appropriate taxonomic key. They were obtained from a commercial supplier on May 6, 1999. Prior to testing fish were maintained under flow-through conditions and were fed a commercial flake food daily during acclimation except for the 48 hours immediately preceding the test initiation. Fish were not fed during the test. Nominal concentrations were 0, 3.9 6.5, 11 18, and 30 mg/L based on a range-finding test. The first definitive test was attempted under daily renewal conditions but was repeated after poor analytical recoveries of the test material. The second definitive test was also repeated because of poor recoveries. The final definitive toxicity test was conducted for 96 hours from May 24 to 28, 1999. Nominal concentrations were 2.6, 4.3, 7.2, 12, and 20 mg/L. It was performed under static renewal conditions and fish were transferred daily to vessels containing freshly prepared solutions.

Ten rainbow trout were indiscriminately distributed to each of two replicates of each treatment. The test was performed in 3.8-liter glass jars that contained 3.0 liters of test solution. Test vessels were randomly arranged in a water bath during the test. A 16-hour light and 8-hour dark photoperiod was automatically maintained with cool-white fluorescent lights that provided a light intensity of approximately 80 foot-candles. The number of surviving organisms, the occurrence of sub lethal effects, and observations of insolubility were determined visually and recorded initially and after 24, 48, 72, and 96 hours. Dead organisms were removed every 24 hours or when first observed.

Results of the toxicity test were interpreted by standard statistical techniques. The 24 hour LC50 was calculated by the binomial method and the 48, 72, and 96 hour LC50 values and slope of the concentration-response curve were determined using the probit method. The no observed effect concentration (NOEC) is the highest concentration of test substance that allowed at least 95% survival and did not cause any sub lethal effects.

Species:	Rainbow Trout ( <i>Oncorhynchus mykiss</i> )
Test Concentration:	0 (control), 2.56, 4.09, 6.44, 10.7, and 18.5 mg/L (measured)
Exposure Period:	96 hours
Analytical Monitoring:	Analytical determination of test substance concentration was performed from each concentration at the beginning and end of the test. Samples were analyzed using a gas chromatograph equipped with an electron capture detector and an HP Chem DOS data system.
GLP:	Yes

Year: 1999

Results: Insoluble material was not observed at any time during the test. Mean measured concentrations of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester were ND (none detected at or above the quantitation of 0.354 mg/L; control), 2.56, 4.09, 6.44, 10.7, and 18.5 mg/L. Mean measured concentrations were 89 to 98% of nominal values, and were stable during the 96-hour test.

Ninety-five percent survival occurred in the control and no sub lethal effects were noted in the control at the end of the exposure period. During the definitive toxicity test the conductivity range was 150 to 180 umhos/cm (mean = 160 umhos/cm), the pH ranged from 7.0 to 7.9, the temperature ranged for 12.0 to 12.9 °C (mean = 12.6 °C), and the dissolved oxygen concentration ranged from 5.9 to 9.8 mg/L (mean = 8.5 mg/L).

Exposure of rainbow trout to the test substance resulted in a 96-hour LC50 of 3.01 mg/L (95% confidence interval = 2.63 to 3.39 mg/L) and a 96-hour NOEC of less than 2.56 mg/L. The slope of the 96-hour dose response curve is 9.7.

Data Quality: 1a

References: Acute Toxicity of DV Methyl Ester to the Rainbow Trout, *Oncorhynchus mykiss*). T.R. Wilbury Laboratories, Inc.; Study Number 1580-FM, FMC Study Number A98-4810

## 11. CHRONIC TOXICITY TO AQUATIC PLANTS

Test Substance: Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester (99.3%)

Method: U.S. EPA FIFRA Subdivision J, 123-2

The toxicity of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester to the freshwater algae, *Selenastrum capricornutum*, was conducted for FMC Corporation for 120 hours from February 3 to 8, 1999 at T.R. Wilbury Laboratories, Inc., in Marblehead, Massachusetts.

The test was conducted under static conditions at 24 +/- 2°C with five concentrations of test substance and a dilution water control. The dilution water was sterile enriched medium adjusted to pH of 7.5 +/- 0.1. The number of cells/mL was determined microscopically using a haemocytometer every 24 hours during the exposure. Based on range-finding tests, nominal concentrations used were 0 mg/L (control), 2.0, 4.0, 7.9, 16, and 32 mg/L.

Algae used in the test were obtained from a culture procured from the Culture Collection of Algae at the University of Texas at Austin and delivered to T.R. Wilbury Laboratories, Inc. The culture was transferred to sterile enriched media identical to media used for the test and maintained at test conditions for more than 14 days before the definitive test. The sub-sample of algae used to inoculate media at the start of the test came from a five day old culture.

Algae were distributed among four replicates of each treatment at approximately 3,000 cells/mL. The fourth replicate was established to allow the measurement of pH at 72 hours. Test vessels were 250 mL glass flasks that contained 50 mL of test solution. Vessels were capped with inverted glass beakers and randomly arranged on a rotary shaker that was adjusted to 100 rpm and located in an incubator during the test. A 24-hour light and 0-hour dark photoperiod was automatically maintained with a light intensity of 4,300 to 4,400 lux.

The number of algal cells/mL in each test vessel and the occurrence of relative size differences, unusual cell shapes, colors, flocculations, adherence of cells to test containers, or aggregation of cells was determined microscopically using a haemocytometer. Temperature of the incubator was measured and recorded daily, and pH was determined in each test vessel at the beginning and end of the test. The pH of each fourth replicate was determined at 72 hours. The temperature of a representative flask of water incubated among the test vessels was recorded continuously.

Results of the toxicity test were interpreted by standard statistical methods. The average specific growth rate was calculated as the natural log of the number of cells/mL at 24, 48, 72, 96 and 120 hours of exposure, minus the natural log of the number of cells/mL at 0 hours of exposure, divided by the hours of exposure. All statistical analyses were performed using the number of cells/mL and the average growth rate, both with the measured concentrations of test substance.

Species:

*Selenastrum capricornutum*

Test Concentration:

<0.373 mg/L; (control), 2.00, 3.76, 7.63, 15.9 and 31.1 measured

Exposure Period:	120 hours
Analytical Monitoring:	Analytical determination of test substance concentration was performed from each concentration at the beginning and end of the test. Samples were analyzed using a gas chromatograph equipped with an electron capture detector and an HP Chem DOS data system. Aliquots were extracted, partitioned and concentrated prior to being analyzed.
GLP:	Yes
Year:	1999
Results:	<p>The 24-hour EC25 and EC50 could not be calculated because growth at all tested concentrations and the control was less than 10,000 cells/mL. The 48, 72, 96 and 120-hour effective concentrations were calculated using the weighted least squares non-linear regression estimation procedure. The 120-hour no observed effect concentration for algae growth was also calculated. A Chi<sup>2</sup> test was used to determine that data were normally distributed and Bartlett's test was used to determine that variances were homogeneous. Based on these results, a one-way analysis of variance and Dunnett's test were used to compare treatment and control data.</p> <p>Insoluble material was not observed at any time during the test. Initial measured concentrations of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester were &lt;0.373 mg/L (control), 2.00, 3.76, 7.63, 15.9 and 31.1 mg/L. Initial measured concentrations were 94 to 100% of nominal values but final concentrations averaged 5.5 to 29%. For this reason, initial measured concentrations were used for all calculations. The algal population in the control vessels grew well, increasing from an average of 3,000 cells/mL to an average of 5,927,000 cells/mL after 120 hours of exposure. Water quality throughout the test was within acceptable limits. The range of the incubator temperatures was 23.5 to 23.7°C and the pH of test media was not significantly affected by the test substance at the beginning of the test.</p> <p>Exposure of <i>Selenastrum capricornutum</i> to cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester for 120 hours resulted in a median effective concentration (EC50) of 8.03 mg/L when using the number of cells/mL and 8.69 mg/L when calculated using the average specific growth rate. The 120-hour NOEC is 3.76 mg/L when calculated using either the number of cells/mL or the average specific growth rate.</p>
Data Quality:	1a
References:	Growth and Reproduction Toxicity Test with DV Methyl Ester and the Freshwater Alga, <i>Selenastrum capricornutum</i> . T.R. Wilbury Laboratories, Inc.; Study Number 1582-FM, FMC Study Number A98-4808

## 12. ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Test Substance: Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester (99.3%)

Method: U.S. EPA FIFRA 72-2

The acute toxicity under static renewal conditions of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester to the daphnid, *Daphnia magna*, was conducted for FMC Corporation for 48 hours from February 15 to 17, 1999 at T.R. Wilbury Laboratories, Inc., in Marblehead, Massachusetts.

The test was performed at 20 +/- 1°C with five concentrations of test substance and a dilution water control. The dilution water was deionized water collected at Marblehead, MA and adjusted to a hardness of 160 to 180 mg/L as CaCO<sub>3</sub>. The pH of the dilution water was adjusted to less than 8.0 prior to use. The dissolved oxygen concentration was always at least 7.6 mg/L.

Juvenile daphnids used in the test were obtained from an in-house culture that was acclimated to test conditions for more than seven days at T.R. Wilbury Laboratories. During the acclimation period, the daphnia culture was supplied yeast/trout chow suspension and *Selenastrum capricornutum* daily. Daphnids were not fed during the test. Based on range-finding tests, nominal concentrations tested were 0mg/L (control) 3.9, 6.6, 11, 18 and 30 mg/L. The loading rate during the test was approximately 14 mg/L and it was less than or equal to 40 daphnids per liter. All animals were in good condition at the beginning of the study.

Ten daphnids were indiscriminately distributed to each of two replicates of each treatment concentration. The test was performed in 300 mL glass beakers that contained 250 mL of test solution. Test vessels were randomly arranged in a water bath for the 48-hour test. A 16-hour light and 8-hour dark photoperiod was automatically maintained at approximately 50 footcandles. Aeration was not required to maintain dissolved oxygen above acceptable limits. The number of surviving organisms, the occurrence of sub-lethal effects, and observations of insolubility were determined visually and recorded initially and after 24 and 48 hours. Dead organisms were removed every 24 hours or when first observed.

Statistical methods were used to determine the 24 and 48-hour LC50 values and 24 and 48-hour EC50 values. Calculations were performed using the binomial or probit method and mean measured concentrations of test substance.

Species: Daphnid, *Daphnia magna*



Test Concentration:	0 (control), 3.04, 5.13, 9.01, 14.6 and 23.6 mg/L(measured)
Exposure Period:	48 hours
Analytical Monitoring:	Analytical determination of test substance concentration was performed from each concentration at the beginning and end of the test. Samples were analyzed using a gas chromatograph equipped with an electron capture detector and an HP Chem DOS data system. Aliquots were extracted, partitioned and concentrated prior to being analyzed.
GLP:	Yes
Year:	1999
Results:	<p>After 48 hours of exposure the control organisms had an average wet weight (blotted dry) of 0.34 mg. Insoluble material was not observed at any time during the test. Mean measured concentrations of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester were ND (none detected at or above the quantitation of 0.373 mg/L; control), 3.04, 5.13, 9.01, 14.6 and 23.6 mg/L. Mean measured concentration were 78 to 82% of nominal values.</p> <p>One hundred percent survival occurred in the control and no sub-lethal effects were noted in the control during the exposure period. The conductivity ranged from 600 to 610 umhos/cm, the pH ranged from 7.4 to 7.6, the temperature ranged from 20.2 to 21.1°C, and the dissolved oxygen concentration ranged from 8.5 to 8.9 mg/L.</p> <p>Exposure to daphnids with cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester resulted in a 48-hour median lethal concentration (LC50) of 7.04 mg/L (95% confidence interval = 6.03 to 8.19 mg/L) and a 48-hour median effective concentration (EC50) of 6.40 mg/L (95% confidence interval = 5.13 to 9.01 mg/L). The 48-hour NOEC is 3.04 mg/L. At 9.01 mg/L test concentration, organisms experienced immobilization at the 24 and 48 hour observations.</p>
Data Quality:	1a
References:	Acute Toxicity of DV Methyl Ester to the Daphnid, <i>Daphnia magna</i> . T.R. Wilbury Laboratories, Inc.; Study Number 1581-FM, FMC Study Number A98-4809

## TOXICITY

### 13. ACUTE TOXICITY

#### A. ORAL

Test Substance: Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester (>98%)

Method: US EPA, 1982, Subdivision F, Hazard Evaluation, 81-1

An acute oral LD50 study was conducted with test material administered undiluted by gavage. Young adult Sprague-Dawley rats were received from Taconic Farms, Germantown, New York. The rats were randomized into their cages using a computer-generated table of random numbers. The animals were acclimated for a minimum of seven days. The condition of the animals was examined prior to formally being released for the study. Fresh tap water and Purina Laboratory Rat Cow 5001 were provided *ad libitum*. Room temperature is to be maintained from 70°F +/- 10°F during the study, and relative humidity will be monitored daily. The animals were individually housed in stainless steel suspended rat cages and maintained in a room with a 12-hour fluorescent light and 12-hour dark cycle.

Animals were fasted overnight prior to dosing. Immediately prior to dosing, male body weights ranged from 217 to 236 grams and female weights were between 201 and 230 grams. The 5000 mg/kg dose of test material was administered as a single treatment via gavage directly into the stomach of each animal approximately four hours after initiation of the light cycle. Observations for mortality and clinical signs were conducted at 0.5, 1, 2, 3, 4 and 6 hours on the day of dosing and twice daily for 13 days. On day 14 the animals were observed once. Body weights were recorded on days 0, 7 and 14 of study. Animals dying intercurrently were weighed upon discovery of death. Gross necropsies were performed on all animals that died during the study. Survivors were euthanized with CO2 gas on day 14 and submitted to gross necropsy.

Species/strain: Sprague-Dawley rats

Sex: Males and females

No. Animals/Group: 5/sex/group

Post dosing observation period: 14 days

GLP: Yes

Year: 1985

Results:

Room temperature was maintained from 70°F to 78°F during the study, while relative humidity ranged from 42% to 57%. Predominant clinical signs included abdominogenital staining, ataxia, chromodacryorrhea, chromorhinorrhea, cyanosis, diarrhea, exophthalmos, lacrimation, decreased locomotion, oral discharge, prostration and recumbency. One female rat died within three days of dosing. All surviving rats returned to normal by the 5<sup>th</sup> day of the study. All surviving animals gained weight during the study. At necropsy, one rat had a mass located in the anogenital area between the skin and muscle layers gross

The test material is classified as practically non-toxic to adult rats under the conditions of this study. The oral LD50 is greater than 5,000 mg/kg in both male and female rats.

Data Quality:

1a

References:

Acute Oral Toxicity of FMC 39338 in Rats, FMC Toxicology Laboratory, FMC Study Number A84-1410

## B. INHALATION

Test Substance:

Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester (>98%)

Method:

No guideline mentioned.

Young adult Sprague-Dawley rats were received from Taconic Farms, Germantown, New York. The animals were randomized into their cages using a computer-generated table of random numbers. The condition of the animals was examined prior to being formally released for the study. Fresh tap water and Purina Laboratory Chow 5001 were available *ad libitum*, except during exposure. The animals were individually housed in stainless steel suspended rat cages and maintained in a room with a 12-hour fluorescent light and 12-hour dark cycle.

Two groups (exposure and control) of five male and five female rats each were used for this study. Male body weights ranged from 262 grams to 302 grams and female body weights ranged from 232 grams to 261 grams immediately prior to exposure. The test chamber was made of stainless steel and glass and had a volume of 100 liters. The chamber air was exhausted from the bottom of the chamber and passed through a commercial airline filter, containing particulate and organic vapor cartridges. The exhaust was powered by a laboratory vacuum pump at a flow rate of 20 liters per minute, creating a slightly negative pressure in the chamber, which was considered to be the total chamber airflow rate. The entire exposure system and exhaust filter were contained in a fume hood. The calculated 99% equilibrium time for the chamber at a flow rate of 20L/min was 23 minutes (equivalent to 12 air changes per hour). The test animals were randomly assigned to and housed in individual compartments of a wire mesh cage bank (all on the same horizontal level) of the test chamber.

The rats were exposed to saturated vapors of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester for six hours at a nominal concentration of 38.7 ppm in a dynamically operated, whole-body inhalation exposure chamber. Chamber air samples were taken continuously with a Bendix THC analyzer, calibrated for methane, during the exposure. Readings each 30 minutes were used to determine the airborne concentration of test material. At the end of exposure, the chamber was cleared for 31 minutes by drawing room air through it at the same flow rate as the test material prior to removing the animals from the chamber. The control group was sham-exposed using room air only and the same basic exposure system. Chamber air temperature and relative humidity were monitored continuously during the exposure with wet/dry bulb hygrometers mounted inside the chambers at 30-minute intervals.

Observations for toxicity and mortality were performed every fifteen minutes during the first hour of exposure, hourly for the remainder of exposure, upon removal from the chamber, at seven hours post-exposure, twice daily thereafter for thirteen days and once on day 14. Individual body weights were recorded immediately prior to exposure (day 0) and on days 7 and 14. Animals dying intercurrently were weighed upon discovery of death. Gross necropsies were performed on all animals which died during the study. On day 14, all surviving animals were sacrificed and gross necropsy examinations were performed.

Species/strain:	Sprague-Dawley rats
No. Animals:	5 male and 5 females (for exposure and control)
Dose:	0.353 mg/L or 38.7 ppm (nominal)
Vehicle:	undiluted
Exposure Period:	6 hours
Post-exposure observations:	14 days
GLP:	Yes
Year:	1987
Results:	<p>Chamber air mean temperature was 75°F and the mean relative humidity was 40% for the exposure group. The mean temperature was 76°F and the mean relative humidity was 44% for the control group. A total of 2.54 g of cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester was delivered in a total volume of 7200 L of air, yielding a nominal concentration exposure of 0.353 mg/L, approximately 38.7 ppm. The mean measured airborne test material concentration was 108 ppm "methane equivalents". The recorder trace of the analyzer output indicated that there was a constant, relatively stable output of vapor from the evaporation system throughout the exposure. Since the correlation of responses between "methane equivalents" and actual concentration of the test material is unknown, this measurement serves only to show stability of the airborne concentration of test material and the nominal concentration is used as the best estimate of exposure concentration.</p> <p>There were no deaths during the study. Clinical signs noted among test rats during and shortly after exposure included squinting eyes, excessive lacrimation, red perinasal fur and irregular breathing patterns. All rats had recovered by study day 1 and remained healthy until termination. All rats gained weight during the study except for one rat. There were no gross treatment-related lesions observed in any animal at necropsy. One rat in the exposure group had a herniated liver.</p>

This finding was judged to be a developmental anomaly commonly found in this strain of rat and is not considered to be related to treatment. The test material produced only transient signs of irritation at an essentially saturated vapor concentration. Therefore, an acute inhalation toxicity hazard is extremely unlikely.

Data Quality:

2e

References:

FMC 39338 Technical, Acute Inhalation Toxicity Screen in Rats, FMC Toxicology Laboratory, FMC Study Number A85-1657

#### 14. GENETIC TOXICITY IN VITRO

Test Substance:

Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester

Method:

EPA Guideline, 1983

Type:

*Salmonella*/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test). Each treatment was run in triplicate with and without metabolic activation by rat liver microsomes. Induced with Aroclor 1254. Solubility and toxicity to bacterial were determined prior to the assay. Positive controls included sodium azide, 9-aminoacridine, and 2-nitrofluorene without S9 and 2-anthramine with S9. The negative control was the vehicle, DMSO.

System of Testing:

*S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538

Concentration:

50, 100, 250, 500 and 1000 ug/plate with and without S9

Metabolic Activation:

With and without S9

GLP:

Yes

Year:

1986

Results:

The test article did not cause a positive response in any of the tester strains with or without metabolic activation. The positive controls gave the expected increase in mutant frequency. The positive and negative controls met the criteria for a valid test. The test article is considered not mutagenic in this assay.

Data Quality:

1a

References:

"Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames test)," FMC Corporation Genetic Toxicology Laboratory, FMC Study Number A84-1451. April 6, 1986; Mutation Research 48, 121-130, 1977

**15. REPEATED DOSE TOXICITY**

No data available

**16. REPRODUCTIVE TOXICITY**

No data available

**17. DEVELOPMENTAL TOXICITY**

No data available

## CRITERIA FOR RELIABILITY CODES

(Adapted from Klimisch et al 1997)

<u>Code of Reliability</u>	<u>Category or reliability</u>
<b>1</b>	<b><u>Reliable without restriction</u></b>
1a	GLP guideline study (OECD, EC, EPA, FDA, etc.)
1b	Comparable to guideline study
1c	Test procedure in accordance with generally accepted scientific standards and described in sufficient detail
<b>2</b>	<b><u>Reliable with restrictions</u></b>
2a	Guideline study without detailed documentation
2b	Guideline study with acceptable restrictions
2c	Comparable to guideline study with acceptable restrictions
2d	Test procedure in accordance with national standard methods with acceptable restrictions
2e	Study well documented, meets generally accepted scientific principles, acceptable for assessment
2f	Accepted calculation method
2g	Data from handbook or collection of data
<b>3</b>	<b><u>Not reliable</u></b>
3a	Documentation insufficient for assessment
3b	Significant methodological deficiencies
3c	Unsuitable test system
<b>4</b>	<b><u>Not assignable</u></b>
4a	Abstract
4b	Secondary literature
4c	Original reference not yet available
4d	Original reference not yet translated
4e	Documentation insufficient for assessment